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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,324	10/13/2006	Bob Coyne	14923.0035	4626

27890 7590 08/14/2009

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EXAMINER	
CHEN, CATHERYNE	
ART UNIT	PAPER NUMBER
1655	
MAIL DATE	DELIVERY MODE
08/14/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/568,324	COYNE ET AL.	
	Examiner	Art Unit	
	CATHERYNE CHEN	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-10,15-51,63 and 68-77* is/are pending in the application.

4a) Of the above claim(s) *37 and 38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-10, 15-36, 39-51, 63, 68-77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/6/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Currently, Claims 1, 3-10, 15-51, 63, 68-77 are pending. Claims 1, 3-10, 15-51, 63, 68-77 are examined on the merits. Claims 2, 11-14, 52-58, 64-67 are canceled.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Applicant's election without traverse of Group I (Claims 1-51, 59-64, 66-67, newly added 68-77), the species Lactococcus-derived bacteriocin, rosemary, phenolic diterpene being carnosic acid, phenolic triperpene being ursolic acid, raw meat, citric acid esters of monodiglycerides, polyphosphates in the reply filed on June 22, 2007 is acknowledged. Claims 37-38 are withdrawn.

Response to Arguments

Claim Rejections - 35 USC § 103

Claims 1, 3-10, 15-36, 39-40, 50-51, 63, 69-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bicchi et al. (2000, Phytochemical Analysis, 11, 236-242), Yang et al. (2001, Bioorganic & Medicinal Chemistry, 9, 347-356), Pol et al. (1999, Letters in Applied Microbiology, 29, 166-170), and Karatzas et al. (2000, J.

Applied Microbiology, 89, 296-301) for the reasons set forth in the previous Office Action, which is set forth below. All of Applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive.

Bicchi et al. teaches rosemary extracts of phenolic diterpenes, rosmarinic acid and caffeic acids, carnosic acid and carnosol (Introduction, paragraph 1). Rosemary is considered to intrinsically teach the claimed phenolic diterpenes, triterpenes, ursolic acid and rosmarinic acid because both the reference and the claimed invention are using the same composition. Phenolic diterpenes are antimicrobials (see Yang et al., Abstract).

However, it does not teach nisin, carvacrol, carvone, and claimed concentrations.

Pol et al. teaches nisin is produced by Lactococcus lactis and is bactericidal against a broad range of Gram-positive bacteria (Introduction, paragraph 1). By combining nisin with plant essential oils, the restrictions in the use of nisin as a food preservative might be overcome and the range of applications could be expanded (Introduction, paragraph 2). Nisin is combined with carvacrol to determine bacteriostatic or bactericidal action of nisin and carvacrol (page 167, Results and Discussion, paragraph 2). Nisin and carvacrol concentrations of inhibition are temperature dependent (Table1). Concentration of nisin used is 5.3 microgram/mL and carvacrol is 0.7 mmol/L (Figure 1); 0.3 microgram/mL of nisin (Figure 2). Synergy between nisin and carvacrol enables use of lower amounts of both compounds for effective food preservation (page 169, right column, first sentence).

Karatzas et al. teaches carvone against Listeria monocytogenes (Abstract) at 5 mmol/L at 45 degree Celsius for 30 minutes (Discussion, paragraph 1). Carvacrol, thymol reduced viable numbers of L. monocytogenes grown at 8 degree Celsius at concentrations of 1.75 mmol/L, 1.5 mmol/L (page 300, paragraph 2). The design of effective combined processing is a complicated task that depends on a great number of factors such as microbial target, the nature of the food, and consumer requirements and legislation (page 300, right column, paragraph 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add nisin, carvacrol and carvone to antimicrobials and rosemaric acid because nisin, carvacrol and carvone are antibacteriocidal and can preserve food. One would have been motivated to make add nisin, carvacrol and carvone for the expected benefit of making an antimicrobial composition. Pol et al. teaches nisin is produced by Lactococcus lactis and is bactericidal against a broad range of Gram-positive bacteria (Introduction, paragraph 1). Karatzas et al. teaches carvone against Listeria monocytogenes (Abstract). Absent evidence to the contrary, there would have been a reasonable expectation of success in making the claimed invention from the combined teachings of the cited references.

MPEP 2144.05 Obviousness of Ranges

II. OPTIMIZATION OF RANGES

A. Optimization Within Prior Art Conditions or Through Routine Experimentation Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges

by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facieobvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molarproportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

> Thus, through routine experimentation, "[t]he normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages." In other words, the claimed amounts were well within the purview of the ordinary artisan at the time the invention was made in an effort to optimize the desired results.

Applicant argues that there is no reason to combine the ingredients.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in

the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Pol et al. teaches nisin is produced by Lactococcus lactis and is bactericidal against a broad range of Gram-positive bacteria (Introduction, paragraph 1). Bicchi et al. teaches rosemary extracts of phenolic diterpenes, rosmarinic acid and caffeic acids, carnosic acid and carnosol (Introduction, paragraph 1), where phenolic diterpenes are antimicorbials (see Yang et al., Abstract). Karatzas et al. teaches carvone against Listeria monocytogenes (Abstract). Thus, it would be obvious to combine ingredients with antibacterial activities together.

Applicant argues that there is unexpected result.

In response to Applicant's argument, Table 5 shows minimal inhibitory concentration for nisin, rosmarinic acid, and phenolic diterpenes. However, the claims are drawn toward nisin comprising less than 0.075% carvacrol and less than 15% cavone, and greater than 1% phenolic diterpene. Nisin components are shown in Table 5. Therefore, the result is not commensurate in scope with claim ingredients and amounts. Thus, the claim of unexpected result is unfounded.

Claims 1, 3-10, 15-36, 39-41, 50-51, 63, 69-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bicchi et al. (2000, Phytochemical Analysis, 11, 236-242), Yang et al. (2001, Bioorganic & Medicinal Chemistry, 9, 347-356), Pol et al. (1999, Letters in Applied Microbiology, 29, 166-170), Karatzas et al. (2000, J. Applied Microbiology, 89, 296-301) as applied to claims 1, 3-10, 15-36, 39-40, 50-51, 63, 69-77 above, and further in view of Bard et al. (US 3679434) for the reasons set

forth in the previous Office Action, which is set forth below. All of Applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive.

The teachings of Bicchi et al., Yang et al., Pol et al., Karatzas et al. are set forth above and applied as before.

The combination of Bicchi et al., Yang et al., Pol et al., Karatzas et al. do not specifically teach the raw meat.

Bard et al. teaches fresh (uncured) meat with edible polyphosphate salts to prevent the development of rancidity (column 2, lines 65-69).

Meat can be spoiled by bacteria and undergoes oxidation. Thus, an artisan of ordinary skill would reasonably expect that anti-oxidants, antimicrobicidals, agents to prevent rancidity could be used as the types of composition taught by the references. This reasonable expectation of success would motivate the artisan to use all of the claimed ingredients in the reference composition. Thus, using all of the claimed ingredient is considered an obvious modification of the references.

MPEP 2144.05 Obviousness of Ranges

II. OPTIMIZATION OF RANGES

A. Optimization Within Prior Art Conditions or Through Routine Experimentation Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facieobvious over a reference process which differed from the claims only in that the reference

process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molarproportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

Thus, through routine experimentation, "[t]he normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages." In other words, the claimed amounts were well within the purview of the ordinary artisan at the time the invention was made in an effort to optimize the desired results.

Applicant argues that there is no reason to combine the teachings of Karatzas.

In response to Applicant's argument, Karatzas et al. teaches carvone against Listeria monocytogenes (Abstract) at 5 mmol/L at 45 degree Celsius for 30 minutes (Discussion, paragraph 1). Carvacrol, thymol reduced viable numbers of L. monocytogenes grown at 8 degree Celsius at concentrations of 1.75 mmol/L, 1.5 mmol/L (page 300, paragraph 2). Thus, there is no temperature limitation for the use of carvacrol. It is known that enzymatic reactions tend to increase with temperature up to

a certain point. The fact that carvacrol worked better at 45 degree C than at 8 degree C is expected. However, the reference does not limit use to only 45 degree C.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use carvacrol because it has activity against bacteria. One would have been motivated to make antimicrobial agent with carvacrol for the expected benefit of killing bacteria. Absent evidence to the contrary, there would have been a reasonable expectation of success in making the claimed invention from the combined teachings of the cited references.

Applicant argues that Bard does not teach using antimicrobials on raw meat.

In response to Applicant's argument, Bard et al. teaches fresh (uncured) meat with edible polyphosphate salts to prevent the development of rancidity (column 2, lines 65-69). Meat can be spoiled by bacteria and undergoes oxidation. Thus, an artisan of ordinary skill would reasonably expect that anti-oxidants, antimicrobicidals, agents to prevent rancidity could be used as the types of composition taught by the references. This reasonable expectation of success would motivate the artisan to use all of the claimed ingredients in the reference composition. Thus, using all of the claimed ingredient is considered an obvious modification of the references.

Claims 1, 3-10, 15-36, 39-43, 50-51, 63, 69-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bicchi et al. (2000, Phytochemical Analysis, 11, 236-242), Yang et al. (2001, Bioorganic & Medicinal Chemistry, 9, 347-356), Pol et al. (1999, Letters in Applied Microbiology, 29, 166-170), Karatzas et al. (2000, J.

Applied Microbiology, 89, 296-301), Bard et al. (US 3679434) as applied to claims 1, 3-10, 15-36, 39-41, 50-51, 63, 69-77 above, and further in view of Todd, Jr. (US 5084293) for the reasons set forth in the previous Office Action, which is set forth below. All of Applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive.

The teachings of Bicchi et al., Yang et al., Pol et al., Karatzas et al., Bard et al. are set forth above and applied as before.

The combination of Bicchi et al., Yang et al., Pol et al., Karatzas et al., Bard et al. do not specifically teach the emulsifier of citric acid esters of mono-diglycerides.

Todd, Jr. teaches antioxidant use for meats (column 1, lines 56-60), rosemary in food stuff (column 5, lines 55-58), emulsifier of citric acid esters of mono-diglycerides (column 18, line 18).

Meat can be spoiled by bacteria and undergoes oxidation. Thus, an artisan of ordinary skill would reasonably expect that anti-oxidants, antimicrobicidals, agents to prevent rancidity could be used as the types of composition taught by the references. This reasonable expectation of success would motivate the artisan to use all of the claimed ingredients in the reference composition. Thus, using all of the claimed ingredient is considered an obvious modification of the references.

Applicant argues that Todd does not teach antimicrobial agents.

In response to Applicant's argument, Todd, Jr. teaches antioxidant use for meats (column 1, lines 56-60), rosemary in food stuff (column 5, lines 55-58), emulsifier of citric acid esters of mono-diglycerides (column 18, line 18). Meat can be spoiled by

bacteria and undergoes oxidation. Thus, an artisan of ordinary skill would reasonably expect that anti-oxidants, antimicrobicidals, agents to prevent rancidity could be used as the types of composition taught by the references. This reasonable expectation of success would motivate the artisan to use all of the claimed ingredients in the reference composition. Thus, using all of the claimed ingredient is considered an obvious modification of the references.

Claims 1, 3-10, 15-36, 39-51, 63, 69-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bicchi et al. (2000, Phytochemical Analysis, 11, 236-242), Yang et al. (2001, Bioorganic & Medicinal Chemistry, 9, 347-356), Pol et al. (1999, Letters in Applied Microbiology, 29, 166-170), Karatzas et al. (2000, J. Applied Microbiology, 89, 296-301), Bard et al. (US 3679434), Todd, Jr. (US 5084293) as applied to claims 1, 3-10, 15-36, 39-43, 50-51, 63, 69-77 above, and further in view of King et al. (US 6451365 B1) for the reasons set forth in the previous Office Action, which is set forth below. All of Applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive.

The teachings of Bicchi et al., Yang et al., Pol et al., Karatzas et al., Bard et al., Todd, Jr. are set forth above and applied as before.

The combination of Bicchi et al., Yang et al., Pol et al., Karatzas et al., Bard et al., Todd, Jr. do not specifically teach the lysozyme, polyphosphates, EDTA.

King et al. teaches antibacterial composition against gram positive bacteristatic of lytic enzymes, bacteriocins apply to solid food (Abstract), use of nisin as bactericides

against bacterium Lactoccus lactis and against gram negative bacteria (column 2, lines 43-59), with lysozyme, polyphosphates, EDTA (column 3, lines 27-32).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add lysozyme, phosphates, EDTA to food because these chemicals are used with nisin as a bacteriocide. One would have been motivated to make the composition with lysozyme, phosphates, EDTA for the expected benefit of making a antibacterial composition. Absent evidence to the contrary, there would have been a reasonable expectation of success in making the claimed invention from the combined teachings of the cited references.

Applicant argues that King does not suggest using antimicrobial agents.

In response to Applicant's argument, King et al. teaches antibacterial composition against gram positive bacteristatic of lytic enzymes, bacteriocins apply to solid food (Abstract), use of nisin as bactericides against bacterium Lactoccus lactis and against gram negative bacteria (column 2, lines 43-59), lysozyme, polyphosphates, EDTA (column 3, lines 27-32). Thus antimicrobial agents are taught.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERYNE CHEN whose telephone number is (571)272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Catheryne Chen
Examiner Art Unit 1655

/Michael V. Meller/
Primary Examiner, Art Unit 1655